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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,597	01/25/2002	Christian Eickmeier	1/1186	2930

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EXAMINER

BERNHARDT, EMILY B

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 09/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/057,597

Applicant(s)
EICKMEIER et al.

Examiner
Emily Bernhardt

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1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/18/03
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, and 9-16 is/are rejected.
- 7) ☒ Claim(s) 2-4 and 6-8 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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In view of applicants' response filed 6/18/03 the following still applies.

Claims 9-16 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Reason #2 of the previous action remains notwithstanding applicants' traverse. Where the scope cannot be readily determined as herein compliance with par.two has not been met. If no disease is actually recited as is the case herein, then one needs to address the question raised by the examiner in the previous action. Otherwise, the scope of the claims rejected herein cannot be easily nor conclusively established . Under such conditions the public cannot readily determine if a use not disclosed by applicants infringes or not.

Claims 9-16 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The case law cited by the examiner is believed relevant since in both cases what the state of the art was at the time of filing was a key element in determining

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operability/enablement of the appealed claims. Note also MPEP 2164.05 (a) which emphasizes the same. The abstracts provided by the examiner demonstrate that NHE inhibitors have been shown to be effective for certain uses described herein as indicated previously but not the range of uses embraced by the claims which include from a reading of the specification on p.5 all cancers, fibrotic diseases, kidney failure, etc. See especially first sentence of Hoque abstract. In the absence of any working examples to treat the myriad of disorders recited coupled with the state of the prior art as evidenced at the very least by the abstracts provided this rejection is being maintained. Note Ex parte Sudilovsky 21 USPQ 2d 1702 where reasoning provided by the examiner was held sufficient to uphold the rejection when as herein applicants provided “no additional evidence of operability” commensurate with the broad subject matter claimed and where no working examples were provided in an art that was deemed both undeveloped and unpredictable.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claims 1,5,9 and 13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Eickmeier and Buerger for reasons of record. All 3 prongs of the 103 test have been met as set forth by the examiner in the previous action. The examiner cannot ignore the fact that all permutations of applicants' compounds embraced by claims rejected herein are exemplified in the 2 species previously pointed out. Applicants' urge their invention is not necessarily providing better Na/H inhibitor(s) but those that are less hygroscopic, more soluble and stable. However, the discovery of an additional property does not make otherwise obvious compounds unobvious. Applicant must prove that their compound(s) possess a property that the prior art compound(s) do not possess- not is not disclosed to possess. See In re Best 195 USPQ 430; In re Dillon 16 USPQ 2d 1897. No data is seen for even one instant compound(s) much less the comparative data needed to overcome the present rejection. It may be the compounds having the above superior properties are the hydrate forms, not rejected herein, and thus not relevant to the instant rejection.

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Claims 1,5,9 and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2,6 and 7 of U.S. Patent No. 6,323,207. These claims cover the instant HCl salt form as as can be readily seen from reading the patent claims. Claim 3 is an example of the methanesulfonate salt form previously pointed out as a close variant. This compound is the first species in col. 11 of the US patent.

Claims 2-4, 6-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory

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period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.


EMILY BERNHARDT

PRIMARY EXAMINER

GROUP 1600